

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LIZA VALIDO-SHADE, et al.	:	MDL DOCKET NO. 1203
	:	
v.	:	
	:	CIVIL ACTION
WYETH LLC, et al.	:	NO. 12-20003

**MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9368**

Bartle, J.

October 31, 2014

Plaintiffs Liza Valido-Shade and her husband Tim Shade have sued defendant Wyeth for damages they have allegedly sustained as a result of her ingestion of Wyeth's diet drugs known as Pondimin® and Redux™ ("Fen-Phen"). The action was originally filed in the Court of Common Pleas of Philadelphia County and timely removed to this court on the basis of diversity of citizenship. According to plaintiffs, Valido-Shade took the drugs for a number of months in 1996 and 1997 and was diagnosed in 2010 with pulmonary arterial hypertension ("PAH"), a debilitating and incurable condition. Whether she suffers from PAH and if so whether Wyeth's diet drugs caused her PAH after such a long latency period is hotly disputed.

Wyeth has now filed a Daubert motion and a motion for summary judgment. Wyeth argues that the testimony of plaintiffs' case-specific causation experts, Lewis Rubin, M.D. and Laurence A. Berarducci, M.D. should be excluded and that without this testimony Wyeth is entitled to summary judgment under Rule 56 of the Federal Rules of Civil Procedure.

We note at the outset that Dr. Berarducci stated at his deposition that he does not disagree with anything Dr. Rubin stated at his deposition. Consequently, if Dr. Rubin's testimony is excluded, the testimony of Dr. Berarducci should be excluded.

Plaintiffs are members of the Nationwide Class Action Settlement Agreement ("Settlement Agreement") involving diet drugs which was approved by the court in Pretrial Order ("PTO") No. 1415. As part of the Settlement Agreement, claims involving primary pulmonary hypertension ("PPH"), the former name for PAH, are excluded from the definition of settled claims. The Settlement Agreement contains a detailed definition of PPH. Settlement Agreement § I.46. Those claiming PPH or PAH may sue Wyeth in the tort system. Settlement Agreement §§ I.46, I.53, VII.B.4, VI.B.5.

In Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Products Liability Litigation, 890 F. Supp. 2d 552 (E.D. Pa. 2012), another PAH case, this court faced the question of the admissibility of the expert testimony of Dr. Rubin and Dr. Stuart Rich that diet drugs can cause an individual to develop PPH eleven years after that individual discontinued use of the drugs. In exercising our gate keeping function, we concluded that plaintiffs had met the requirements of qualification, reliability, and fit under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), and Rule 702 of the Federal Rules of Evidence.<sup>1</sup> We noted that it would be up

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1. Rule 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or

to the jury to decide whether to accept the opinions of Drs. Rubin and Rich or those of Wyeth's experts to the contrary. In contrast, we face here Dr. Rubin's case-specific testimony on causation as it relates to Valido-Shade.

Dr. Rubin's case-specific testimony ties the 2010 diagnosis of Valido-Shade's PAH to her ingestion of Wyeth's diet drugs many years earlier in 1996 and 1997. Wyeth, however, argues that Dr. Rubin's testimony should be excluded and relies on the following parts of his expert deposition in this action:

Q. And we really just can't know why she [Valido-Shade] has the disease, right?

A. We - we don't know for sure, but I think I can say more likely than not, 51 percent, that that prior exposure [to diet drugs] cannot be ignored.

. . . .

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education may testify in the form of an opinion or otherwise if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

A. . . . I think the longer they've been on it, the further beyond the magic three-month number, the more likely I am to believe that it could be a contributor. And then they have to have the exclusion by clinical ground or other --

Q. And I've assumed that in the question.

A. Then in that situation, I think you have sufficient scientific evidence to link those two beyond a reasonable degree of medical probability, 51 percent.

Q. . . . If somebody took it [diet drugs] in the past, you can't really know if it's idiopathic or the drug, but you --

Q. -- but you really can't rule it out?

. . . .

THE WITNESS: Well, it's 51/49. . . .

Q. But it could be 51/49 the other way, too, right?

A. It could. It could. So, you know, there could be somebody out there who - who says that it's 49 and, you know, it - sure, that's possible, too. And I - I think it's 51. They think it's 49. And really the only meaningfulness it has is in this litigation. From the standpoint of the patient, it doesn't matter.

Rubin Dep., May 22, 2014, pp. 91, 96-98.

Wyeth maintains that Dr. Rubin's opinion of a 51% probability of causation is insufficient under Pennsylvania law to meet the Commonwealth's more onerous standard that medical causation

must be established to a reasonable degree of medical certainty. Wyeth therefore argues that Dr. Rubin's testimony must be barred. In Paoli Railroad Yard PCB Litigation, 35 F.3d 717, 750-52 (3d Cir. 1994), a toxic tort case, our Court of Appeals explained that Pennsylvania's requirement that causation of a plaintiff's illness must be shown with a reasonable degree of medical certainty constitutes part of a plaintiff's burden of proof. The Court held that the requirement is one of substance calling for the application of state law and is not merely a matter of admissibility where federal rules such as Rule 702 of the Federal Rules of Evidence or Daubert would govern. Paoli Rail Yard controls the analysis in this diversity action.

Wyeth relies on the decision of the Pennsylvania Superior Court in Griffin v. University of Pittsburgh Medical Center, 950 A.2d 996 (Pa. Super. Ct. 2008), to exclude Dr. Rubin's testimony. There, the plaintiff had brought a medical malpractice case arising out of a shoulder injury she suffered in the hospital after an operation for a separate condition. The issue was whether the shoulder injury was caused by a grand mal seizure or by the effects of forcible bed restraint. The plaintiff's expert, Dr. Kevin Speer, testified that his opinion was being given with a reasonable degree of medical certainty, the standard of proof required in Pennsylvania. Yet, in opining that plaintiff suffered from the effects of forcible bed

restraint (which would constitute hospital negligence) rather than a grand mal seizure (which would not constitute hospital negligence), Dr. Speer gave the following testimony on cross-examination:

Q. . . . Am I correct, Dr. Speer, that you are unable to state, with reasonable medical certainty, whether Ms. Griffin's injury was caused by a seizure versus forcible restraint?

A. My answer to your question is not as - as simple as I would like for it to be. I think the two possibilities that could have created her shoulder injury [sic].

One of the two occurred. Unfortunately, there's a void of evidence or a lack of documentation to support either. I think that from a reasonable degree of medical certainty, that is choosing one or the other, a **fifty-one to forty-nine percent** consideration, I think that **the least implausible** consideration would be the - that she was restrained and had - her shoulder was injured in her attempts to be restrained because she was resisting that.

Q. So you're giving that the fifty-one percent?

A. I am, yes, sir.

Griffin, 950 A.2d at 1002 (emphasis in original).

The Superior Court explained that while Dr. Speer had used the "magic words" "reasonable degree of medical certainty," it is the totality and substance of the opinion that is crucial, not the shibboleths uttered. Id. at 1003. The court found his testimony fatally flawed in that he stated that the odds of forcible restraint as the cause of plaintiff's injury were only 51% versus 49% for the



seizure. In effect, Dr. Speer was employing a "more likely than not" standard. Griffin ruled that such a standard of proof is insufficient under Pennsylvania law for a viable expert opinion. Id. It reversed the jury verdict in favor of the plaintiff and ordered judgment to be entered in favor of the hospital. Id. at 1005.

The situation here is virtually the same as in Griffin. Dr. Rubin used the words "reasonable degree of medical probability" and "reasonable degree of medical certainty" at certain times in his deposition.<sup>2</sup> Nonetheless, he testified that the likelihood of the diet drugs causing Valido-Shade's disease was only 51% versus a 49% probability of an idiopathic cause. He specifically equated "beyond a reasonable degree of medical probability" with a 51% likelihood. The substance of his testimony taken as a whole simply does not meet Pennsylvania's requisite level of certitude that the diet drugs caused Valido-Shade's PAH. See Corrado v. Thos. Jefferson Univ. Hosp., 790 A.2d 1027, 1030-31 (Pa. Super. Ct. 2001).

What Dr. Rubin has opined runs afoul of Griffin and thus leaves the plaintiffs without expert testimony that Wyeth's diet drugs, to a reasonable degree of medical certainty, brought about Valido-Shade's PAH after a latency period of some thirteen years. Even if her illness is PAH, plaintiffs cannot prevail against Wyeth

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2. For present purposes, we equate "reasonable degree of medical probability" with "reasonable degree of medical certainty."

without proper expert causation testimony, since a jury cannot find causation in this case without such evidence. Accordingly, reviewing the admissible evidence in the light most favorable to plaintiffs, the court must grant summary judgment in favor of Wyeth as there is now no evidence on causation allowing plaintiffs to go to a jury.<sup>3</sup> See Fed. R. Civ. P. 56; NAACP v. N. Hudson Reg'l Fire & Rescue, 665 F.3d 464, 475 (3d Cir. 2011).<sup>4</sup>

As a result, we need not reach the question raised by Wyeth as to whether plaintiffs meet the admissibility requirements with

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3. At oral argument, plaintiff's counsel for the first time raised the issue of Pennsylvania's choice of law rules. This action, as noted above, was initially filed in the Court of Common Pleas of Philadelphia County and removed to this court. Counsel maintained that the locus of events was Florida and that Florida law should apply. The choice of law issue was not briefed and is now waived. In any event, counsel's position is without merit. He did not identify the Florida standard for burden of proof for expert testimony or whether it differs from Pennsylvania law. Even if Pennsylvania would apply Florida negligence law, product liability law, and law on damages, Pennsylvania law on the burden of proof would still govern. Foley v. Pittsburgh-Des Moines Co., 68 A.2d 517, 521-22 (Pa. 1949), disapproved on other grounds, Smith v. Bell Tel. Co. of Pa., 153 A.2d 477, 479 (Pa. 1959); Carroll v. Godding, 38 A.2d 720, 720 (Pa. Super. Ct. 1944); see also Restatement (Second) of Conflict of Laws § 133 (1971).

4. In their opposition brief, plaintiffs reference the deposition testimony of Dr. Murali Chakinala and Dr. Jeremiah S. Reedy, who were two of Valido-Shade's treating physicians. Both physicians have testified that Valido-Shade has PAH and both have concluded that her use of Wyeth's diet drugs caused her illness. However, neither has been designated by plaintiffs as a causation expert and in any event neither has based his causation conclusion on a reasonable degree of medical certainty.



respect to expert testimony under Daubert or Rule 702 of the Federal Rules of Evidence.